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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,493	01/23/2004	Joseph G. Furst	Icon001	7004
54279	7590	06/17/2005	EXAMINER	
PAUL V. KELLER, LLC 4585 LIBERTY RD. SOUTH EUCLID, OH 44121			GHERBI, SUZETTE JAIME J	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/763,493

Applicant(s)

FURST ET AL.

Examiner

Suzette J Gherbi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/3/04, 9/20/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 41 is objected to because of the following informalities: The end of a sentence should end with a period. Appropriate correction is required.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claims 39-40 mention micro-electro mechanical machining and teeth.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 39-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

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which it pertains, or with which it is most nearly connected, to make and/or use the invention. There is not any description for enablement to manufacture a stent by micro-electromechanical machining used to form teeth or other indentations.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-2, 4-5, 8-9, 12-13, 15-16, 19-23, 31-32, 36-37, 41-42, 44, and 47-49, 52, 54, 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Reich et al. 5,993,972. The invention is clearly understood and the claims as currently written are disclosed by Reich et al. comprising: A graft with a wall forming a lumen (inherent properties of a vascular graft see col. 3, lines 16-20); an amphiphilic block copolymer coating a surface of the wall (col. 3, line 17 "coat", col. 3, lines 50-55, col. 4, lines 7-20 and col. 7, lines 59-60); wherein the amphiphilic block copolymer comprises a network of both hydrophobic and hydrophilic polymer chains/links (col. 4, lines 78; col. 6, lines 43-44); which are *capable of swelling in both hydrophobic and hydrophilic solvents*; wherein the amphiphilic block copolymer coating can carry a drug for inhibiting one or more of stenosis, vascular narrowing and thrombosis (col. 29, lines 51-67; col. 30, lines 1-16); wherein poly(alkylene glycol) chains are utilized; wherein polysiloxanes are

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utilized see col. 33, lines 29-30); wherein a plurality of layers may *act* as a barrier (col. 20, lines 36-40); wherein the graft is bioerodable, and biostable. These are product claims and not method claims therefore the intended use recitation/functional language (i.e. release of about 10-90 percent with the first thirty days of installation; and acts as a barrier; and forms or forming, ect.) of the product claims carries no patentable weight in the absence of any distinguishing structure. Reich et al. clearly discloses the structure as claimed and is found to be inherently capable of performing the function

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 6-7, 10-11, 27, 29-30, 43, 45-46, 50-51, 53, 55, 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reich et al. in view of Furst 6,206,916 and further in view of Hammond 5,880,090. Reich et al. has been disclosed above and mentions a variety of drugs that can be utilized within the coating carrier of amphiphilic block copolymers however, Reich et al. does not mention the drug triazolopyrimidine otherwise known as Trepidil. Furst teaches stent grafts have been known to utilize the drug Trepidil (col. 4, lines 51-67; col. 5, lines 1-57). Hammond et al. teaches the use of GM-CSF (col. 3, lines 21) which is utilized with vascular grafts. It would have been

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obvious to one having ordinary skill in the art at the time the invention was made to utilize the drug Trapidil and/or the GM-CSF with the invention of Reich et al. platelet adhesion to the vascular wall after angioplasty and/or the placement of a stent or for repair after such procedures as chemotherapy because Trapidil is known for it's antithromobotic properties and GM-CSF is known to aid in the treatment of enhancing endothelization.

9. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reich et al. in view of Roorda et al. Reich et al. has been noted above with the presence of copolymer layers (col. 20, lines 37-38 however Reich et al. does not mention that parylene ora derivative thereof has been added. Roorda et al. teaches the use of parylene as a suitable polymer carrier for drugs on grafts and stents. It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the invention of Reich et al. and utiize parylene as taught by Roorda et al. between layers because it is a suitable carriers and could also help to control the rate of release of the agents.

10. Claims 2-3, 17-19, 24-28 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reich et al. in view of Brauker et al. 6,517,571. Reich et al. has been noted however Reich et al. does not specify the term "carpet-like" structure. However Reich et al. does mention that a coated cloth of amphiphilic block copolymer with long chains/links (see col. 29, lines 52-67) can be can be used as a carrier of drugs. Brauker

et al. teaches that e PTFE is known for its pore size (see col. 10, lines 10-25) and can be utilized a cloth type carrier for a variety of drugs (see col. 14, lines 33-39). It would have been obvious to one having ordinary skill in the art at the time the invention was made take the invention/coating of Reich et al. with long chains of a surface with specific pore size in order to control the release rate of the drugs.

11. Claims 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reich et al. in view of Kennedy et al. 6,727,322. Reich et al. has been disclosed however Reich et al. does not specify the processing of the amphiphilic coatings. Kennedy et al. utilizes amphiphilic networks for coatings on vascular devices (col. 18, lines 44-45) and utilizes techniques such as evaporating solvents (col. 15, lines 13-25) and macro-monomers and swelling of the polymers (see col. 21, lines 42-67, col. 22, lines 1-36). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the processing techniques as claimed and presented by Kennedy because both inventions produce amphiphilic polymer coatings for vascular devices.

12. Claims 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reich et al. in view of McGuinness 6,156,062. Reich et al. has been noted and while Reich et al. does note that a variety of vascular devices may be coated Reich et al. does not limit the stent structure (mentioned in col. 10, line 60-62) to any specific structure and/or manufacturing steps. McGuinness teaches that a helically wrapped

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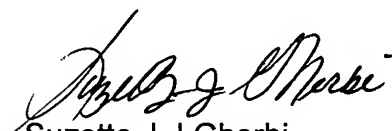
stent can be manufactured by micro machining (col. 6, lines 48-50) and provides a plurality of indentations (28). It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the coating of Reich et al. and utilize a stent structure manufactured by micro machining as taught by McGuinness because it is well known that flexible graft can be supported by the structural integrity of a stent scaffold to prevent migration and prolapse of the graft.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.

14. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

15. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


Suzette J-J Gherbi
13 June 2005